

U.S. Application No.: 10/511,813
RESPONSE TO RESTRICTION REQUIREMENT
SECOND PRELIMINARY AMENDMENT

Attorney Docket: 4007.008

IN THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Claims 1-33 (canceled)

34. (currently amended) A method for detection of disorders characterized by abnormal cell proliferation in an individual comprising

a. detecting the presence or absence and/or the level of expression of human transketolase like-1 gene in a biological sample obtained from said individual; and

b. assessing diagnosis from said presence or absence and/or level of expression, wherein presence of overexpression is indicative of disorders characterized by abnormal cell proliferation.

35 (previously presented) The method according to claim 34, wherein the disorder characterized by abnormal cell proliferation is cancer.

36. (previously presented) The method according to claim 35, wherein the cancer is colon cancer, lung cancer, gastric cancer or pancreatic cancer.

37 (previously presented) The method according to claim 34, wherein the biological sample is a body fluid, a secretion, a smear, a biopsy, a liquid containing cells, lysed cells, cell debris, peptides or nucleic acids.

38. (previously presented) The method according to claim 37, wherein the sample is serum, urine, semen, stool, bile, a biopsy or a cell- or tissue-sample.

{WP297583,1}

- 2 -

U.S. Application No.: 10/511,813
RESPONSE TO RESTRICTION REQUIREMENT
SECOND PRELIMINARY AMENDMENT

Attorney Docket: 4007.008

39. (previously presented) The method according to claim 34, wherein the detection of the expression of the human transketolase like-1 gene is carried out on a polypeptide level.

40. (previously presented) The method according to claim 34, wherein the detection of the expression of the human transketolase like-1 gene is carried out on a nucleic acid level.

41. (previously presented) The method according to claim 39, wherein the detection on the polypeptide level is carried out using a binding agent directed against human transketolase like-1 polypeptides.

42. (previously presented) The method of claim 41, wherein the binding agent is: an antibody, a fragment of an antibody, a peptidomimetic comprising an antigen binding epitope or a mini-antibody.

43. (previously presented) The method according to claim 39, wherein the detection is an immuno-cytochemical detection procedure.

44. (previously presented) The method according to claim 40, wherein at least one nucleic acid probe, hybridizing to a human transketolase like-1 nucleic acid, is used for the detection.

45. (previously presented) The method according to claim 44, wherein the probe is detectably labelled.

46. (previously presented) The method according to claim 45, wherein the label is selected from the group consisting of a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, a metal chelate, or an enzyme.

47. (previously presented) The method according to claim 40, wherein the detection reaction comprises a nucleic acid amplification reaction.

48. (previously presented) The method according to claim 44, wherein the amplification reaction is PCR, LCR or NASBA.

{WP297583.1}

U.S. Application No.. 10/511,813
RESPONSE TO RESTRICTION REQUIREMENT
SECOND PRELIMINARY AMENDMENT

Attorney Docket: 4007.008

49. (previously presented) The method according to claim 40, which is used for in-situ hybridization.

50. (previously presented) The method according to claim 34 which is used in the course of an in vivo or in vitro molecular imaging method.

51. (previously presented) A kit for performing the method of claim 34, which is a research kit or a diagnostic kit.

52. (previously presented) The kit of claim 51 comprising

a. at least one probe for the detection of human transketolase like-1 gene expression products in biological samples;

b. a human transketolase like-1 gene product sample for performing a positive control reaction

53. (previously presented) The kit of claim 52, wherein the probe is a nucleic acid probe, specifically hybridizing to human transketolase like-1 nucleic acids or an antibody specifically binding human transketolase like-1 proteins.

54. (previously presented) A method for treating disorders characterized by abnormal proliferation of cells based on the administration of a pharmaceutical composition containing a human transketolase like-1 gene or gene product in a pharmaceutical acceptable form.

55. (previously presented) The method according to claim 54, wherein the human transketolase like-1 gene or gene product is a nucleic acid in sense or antisense orientation or a polypeptide.

56. (previously presented) The method according to claim 55, wherein the pharmaceutical composition comprises a chimeric nucleic acid comprising a human transketolase like-1 nucleic acid or fragments thereof or a fusion polypeptide comprising a human transketolase like-1

{WP297583;1}

- 4 -

U.S. Application No.: 10/511,813
RESPONSE TO RESTRICTION REQUIREMENT
SECOND PRELIMINARY AMENDMENT

Attorney Docket: 4007.008

polypeptide or fragments thereof.

57. (previously presented) The method according to claim 54, wherein the disorder characterized by abnormal cell proliferation is cancer.

58. (previously presented) The method according to claim 56, wherein the cancer is colon cancer, lung cancer, gastric cancer or pancreatic cancer.

59. (previously presented) The method according to claim 54, wherein the method for treatment is immunotherapy.

60. (previously presented) The method according to claim 54, wherein the method for treatment is vaccination therapy.

61. (previously presented) A method of identifying and obtaining a drug candidate for therapy of tumors of the colon, the lung, the pancreas or the stomach comprising the steps of

a. contacting a TKT-L1 polypeptide as used in the method of the present invention or a cell expressing said polypeptide in the presence of components capable of providing a detectable signal in response to transketolase activity or to altered regulation of cell proliferation, and

b. detecting presence or absence of a signal or increase of the signal generated from transketolase activity or altered regulation of cell proliferation, wherein the absence or decrease of the signal is indicative for a putative drug

62. (previously presented) A pharmaceutical composition for the treatment of tumors of the colon, the lung, the pancreas or the stomach, comprising a compound identifiable by the method according to claim 61, an antithiamine compound, an inhibitor of transketolase enzyme activity, an inhibitor of transketolase like-1 activity, a transketolase like-1 polypeptide or a human transketolase like-1 nucleic acid.

63. (previously presented) A method for rational tumor management comprising

{WP297583;1}

- 5 -

U.S. Application No.: 10/511,813
RESPONSE TO RESTRICTION REQUIREMENT
SECOND PRELIMINARY AMENDMENT

Attorney Docket: 4067.008

- a. detecting the presence or absence and or the level of overexpression of transketolase like-1 gene in biological samples
- b. building of subgroups according to the presence or absence and/or the levels of transketolase like-1 gene
- c. tailoring an adequate therapy according to the subgroups comprising reduction of transketolase like-1 activity in individuals or in cells of individuals.

64. The method according to claim 63, wherein the reduction of the activity of transketolase like-1 is achieved by the administration of antithiamine compounds, of pharmaceutical compositions of claim 63, of inhibitors of transketolase enzyme activity, of transketolase like-1 antisense constructs, of ribozymes specific for transketolase like-1 or by reduced administration of thiamine.